



PATENT
Customer No. 22,852
Attorney Docket No. 03806.0046-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Hervé BOUCHARD et al.)	Group Art Unit: 1625
)	
Application No.: 08/162,984)	Examiner: Ba Trinh
)	
Filed: December 8, 1993)	
)	
For: TAXOIDS, THEIR PREPARATION)	Confirmation No.: 4803
AND PHARMACEUTICAL)	
COMPOSITIONS CONTAINING)	
THEM)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Office the documents on the attached listing. This Information Disclosure Statement is being filed before the mailing date of a first Office Action after the filing of a Request for Continued Prosecution under 37 C.F.R. § 1.129(a) in the above-referenced application.

Copies of the listed documents, excluding any U.S. Patents, U.S. Patent Application Publications, and co-pending U.S. Patent Applications which are available in the Image File Wrapper System, are attached.

Applicants respectfully request that the Office consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

With respect to the foreign language documents, Applicants submit the following:

1. **WO 95/13271** - An English language abstract appears on the first page of this document.
2. **WO 96/01259** - An English language abstract appears on the first page of this document. Applicants additionally submit herewith an English language translation of this document.

Applicants note that the Examiner did not initial the following reference cited on the Form PTO/SB/08 filed January 18, 2005, as no date (year) was provided therein: VYAS et al., "Phosphatase-Activated Prodrugs of Paclitaxel," Taxane Antitumor Agents (ACS Symposium), Mar. 13-17, pp. 124-137. Applicants therefore resubmit the cited reference herein Form PTO/SB/08, establishing the date as March 13-17, 1994.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Office applies any of the documents as prior art against any claim in the application and Applicants determine that the cited document(s) do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

MICHELE C. BOSCH, Reg. No. 40,524

Dated: November 14, 2005

By: Michele C. Bosch
for Thomas L. Irving
Reg. No. 28,619

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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Complete if Known

Application Number	08/162,984
Filing Date	December 8, 1993
First Named Inventor	Hervé BOUCHARD
Art Unit	1625
Examiner Name	Ba Trinh
Attorney Docket Number	03806.0046-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	US-4,924,012	05-08-1990	Colin et al.	
	2.	US-5,670,536	09-23-1997	Durr et al.	
	3.	US-5,698,582	12-16-1997	Bastart et al.	
	4.	US-5,840,931	11-24-1998	Bouchard et al.	
	5.	US-6,911,549	06-28-2005	Hester et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	6.	WO 95/13271	05-18-1995	Bouchard, et al.		English Abstract
	7.	WO 96/01259	01-18-1996	Bouchard, et al.		Yes

NON PATENT LITERATURE DOCUMENTS AND OTHER PATENT APPLICATION DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶
	8.	Declaration of François Lavelle, submitted in U.S. Patent Application No. 08/162,984, dated December 27, 1994.	
	9.	Declaration of François Lavelle, submitted in U.S. Patent Application No. 08/162,984, dated April 14, 1995.	
	10.	Declaration of William C. Rose, submitted in Patent Interference No. 103,675, Chen v. Bouchard, dated March 7, 1996.	
	11.	Declaration of John F. Kadow, submitted in Patent Interference No. 103,675, Chen v. Bouchard, dated March 8, 1996.	
	12.	Declaration of François Lavelle, submitted in Patent Interference No. 103,675, Chen v. Bouchard, dated May 22, 1996.	
	13.	Declaration of William C. Rose, submitted in Patent Interference No. 103,675, Chen v. Bouchard, dated July 3, 1996.	
	14.	Declaration of François Lavelle, submitted in U.S. Patent Application No. 08/162,984, dated November 10, 1999.	
	15.	Chen, et al. Preliminary Motion No. 2, submitted in Patent Interference No. 103,675, Chen v. Bouchard, dated March 11, 1996.	
	16.	Chen, et al. Preliminary Motion No. 3, submitted in Patent Interference No. 103,675, Chen v. Bouchard, dated March 11, 1996.	
	17.	Bouchard et al. Opposition to Chen Preliminary Motion No. 2, submitted in Patent Interference No. 103,675, Chen v. Bouchard, dated May 23, 1996.	
	18.	Bouchard et al. Opposition to Chen Preliminary Motion No. 3, submitted in Patent Interference No. 103,675, Chen v. Bouchard, dated May 23, 1996.	
	19.	Chen, et al. Reply No. 2, submitted in Patent Interference No. 103,675, Chen v. Bouchard, dated July 8, 1996.	

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NON PATENT LITERATURE DOCUMENTS AND OTHER PATENT APPLICATION DOCUMENTS

20.	Chen Reply No. 3, submitted in Patent Interference No. 103,675, Chen v. Bouchard, dated July 8, 1996.	
21.	Withdrawal of Chen, et al. Preliminary Motion No. 2, submitted in Patent Interference No. 103,675, Chen v. Bouchard, received August 20, 1996.	
22.	VYAS et al., "Phosphatase-Activated Prodrugs of Paclitaxel," Taxane Anticancer Agents: Basic Science and Current Status (ACS Symposium Series), Mar. 13-17, 1994, pp. 124-137.	
23.	Copending Application No. 10/858,554 (Reissue of U.S. Patent No. 6,441,026); Attorney Docket No. 03806.0281-14000; Title: ANTITUMOR COMPOSITIONS CONTAINING TAXANE DERIVATIVES AND ALKYLATING AGENTS; U.S. Filing Date: June 2, 2004.	
24.	Office Action in copending Application No. 10/858,554 (Attorney Docket No. 03806.0281-14000), dated April 7, 2005 (Ex. Owens).	
25.	Third-Party Protest filed in copending Application No. 10/858,554 (Attorney Docket No. 03806.0281-14000), dated October 12, 2004.	
26.	Response to Office Action, filed in copending Application No. 10/858,554 (Attorney Docket No. 03806.0281-14000), dated October 7, 2005.	
27.	Copending Application No. 11/165,579; Attorney Docket No. 03806.1506-01000; Title: 7-HALO-AND 7 β , 8 β -METHANO-TAXOLS, ANTINEOPLASTIC USE AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM; U.S. Filing Date: June 24, 2005.	
28.	Exhibit A submitted with Response and Request for Continued Prosecution under 37 C.F.R. § 1.129(a), entitled "Intermediates - First Access to Genus Compounds" and "Intermediates - Second Access to the Genus Compounds."	
29.	Goldstein, L.J., et al., <i>Expression of a Multidrug Resistance Gene in Human Cancers</i> , J. NATL. CANCER INST., Vol. 81, No. 2, pp. 116-124 (1989), attached as Appendix II to April 14, 1995 Declaration of François Lavelle.	
30.	Schabel, F.M., et al., <i>Establishment of Cross-Resistance Profiles for New Agents</i> , CANCER TREATMENT REPORTS, Vol. 67, No. 10, pp. 905-922 (1983), attached as Appendix III to April 14, 1995 Declaration of François Lavelle.	
31.	Bouchard Exhibit 42, Instruction 271B, <i>Summary of the Usual Characteristics of Selected Murine Models Used Under the Auspices of the NCI Division of Cancer Treatment</i> (April 1, 1978), attached as Appendix IV to April 14, 1995 Declaration of François Lavelle.	
32.	Corbett, T.H., et al., <i>Induction and Chemotherapeutic Response of the Two Transplantable Ductal Adenocarcinomas of the Pancreas in C57BL/6 Mice</i> , CANCER RESEARCH, Vol. 44, pp. 717-726 (February 1984), attached as Appendix V to April 14, 1995 Declaration of François Lavelle.	
33.	Chen Exhibit 1, Curriculum Vitae of William Carl Rose, Ph.D., submitted with March 7, 1996, William C. Rose Declaration.	
34.	Chen Exhibit 4, Initial Interference Memorandum (August 10, 1995).	
35.	Chen Exhibit 5, Curriculum Vitae of John F. Kadow, submitted with March 8, 1996, John F. Kadow Declaration.	
36.	Chen Exhibit 6, Prosecution History for U.S. Patent Application No. 08/006,423, filed January 19, 1993.	
37.	Chen Exhibit 7, Prosecution History for U.S. Patent Application No. 07/907,261, filed July 1, 1992.	
38.	Chen Exhibit 8, Magri, et al., <i>Modified Taxols. 3. Preparation and Acylation of Baccatin</i>	

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First Named Inventor

Hervé BOUCHARD

Art Unit

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	III, J. ORG. CHEM., Vol. 51, pp. 3239-42 (1986).	
39.	Chen Exhibit 10, Ojima, et al., <i>Synthesis and Structure-Activity Relationships of New Antitumour Taxoids. Effects of Cyclohexyl Substitution at the C-3' and/or C-2 of Taxotere (Docetaxol)</i> , 37 J. MED. CHEM. 2602-2608 (1994).	
40.	Bouchard Exhibit 10, <i>Rhone-Poulenc's New Drug For Breast Cancer Cleared</i> , THE WALL STREET JOURNAL (May 16, 1996).	
41.	Bouchard Exhibit 11, Udea, et al., <i>Novel, Water-Soluble Phosphate Derivatives of 2'-Ethoxy Carbonylpaclitaxel as Potential Prodrugs of Paclitaxel: Synthesis and Antitumor Evaluation</i> , BIOORGANIC & MEDICINAL CHEM. LTRS., Vol. 5, No. 3, pp. 247-252 (1995).	
42.	Bouchard Exhibit 12, Udea, et al., <i>Novel Water Soluble Phosphate Prodrugs of Taxol Possessing in vivo Antitumor Activity</i> , BIOORGANIC & MEDICINAL CHEM. LTRS., Vol. 3, pp. 1761-1766 (1993).	
43.	Bouchard Exhibit 13, Chen, et al., <i>Serendipitous Synthesis of a Cyclopropane-containing Taxol Analog via Anchimeric Participation of an Unactivated Angular Methyl Group</i> , J. ORG. CHEM., Vol. 58, No. 17, pp. 4520-21 (August 13, 1993).	
44.	Bouchard Exhibit 14, Webster's New Collegiate Dictionary 1050 (1981).	
45.	Bouchard Exhibit 15, Prosecution History for U.S. Patent No. 5,380,751 to Chen et al., filed September 28, 1993.	
46.	Bouchard Exhibit 16, English translation of PCT Application No. 96/01259, published January 18, 1996.	
47.	Bouchard Exhibit 38, Chen, et al., <i>Taxol Structure-Activated Relationships: Synthesis and Biological Evaluation of Taxol Analogs Modified at C-7</i> , BIOORGANIC & MEDICINAL CHEM. LTRS., Vol. 4, No. 18, pp. 2223-28 (1994).	
48.	Bouchard Exhibit 39, D.M. Vyas & J.F. Kadow, <i>Paclitaxel: A Unique Tubulin Interacting Anticancer Agent</i> , PROGRESS IN MEDICINAL CHEM., Vol. 32, pp. 289-337 (1995).	
49.	Bouchard Exhibit 41, Chen et al., <i>Novel C-4 Paclitaxel (Taxol) Analogs: Potent Antitumor Agents</i> , BIOORGANIC & MEDICINAL CHEM. LTRS., Vol. 5, No. 22, pp. 2741-46 (1995).	
50.	Bouchard Exhibit 43, T.H. Corbett et al., <i>Is the P388 Murine Tumor No Longer Adequate as a Drug Discovery Model?</i> , INVESTIGATIONAL NEW DRUGS, Vol. 5, pp. 3-20 (1987).	
51.	Bouchard Exhibit 44, C.H. Nguyen, et al., <i>Further SAR in the New Antitumor 1-amino-Substituted γ-carbolines and 5H-benzo[e]pyrido[4,3-b]indoles Series</i> , ANTICANCER DRUG DESIGN, Vol. 7, pp. 235-251 (1992).	
52.	Bouchard Exhibit 45, F. Lavelle et al., <i>Preclinical Evaluation of Docetaxel (Taxotere)</i> , SEMINARS IN ONCOLOGY, Vol. 22, No. 2, Suppl. 4, pp. 3-16 (April 1995).	
53.	Bouchard Exhibit 63, J.E. Schurig et al., <i>Experimental Antitumor Activity of BMY-28175 A New Fermentation Derived Antitumor Agent</i> , INVESTIGATIONAL NEW DRUGS, Vol. 8, pp. 7-15 (1990).	

Examiner
SignatureDate
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



PTO Notes regarding this form:

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 - ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).
 - ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
 - ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.
 - ⁶ Applicant is to place a check mark here if English language Translation is attached.
- This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**